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Registration Decision RD2015-04

Momfluorothrin

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Registration Decision for Momfluorothrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Momfluorothrin Technical Grade, as well as three manufacturing concentrates: Sumifreeze Manufacturing Use Product, MGK 2983 and MGK 2987; and four domestic class end-use products: Momfluorothrin Flying and Crawling Insect Killer Spray, MGK 29831, MGK 29871 and MGK 29872. All four end-use products are used to control a variety of insect and spider species found indoors and outdoors at residential locations. The end-use products are also coformulated with either d-phenothrin or piperonyl butoxoide.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-21, *Momfluorothrin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Momfluorothrin and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2014-21.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-21, *Momfluorothrin*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website.

What is Momfluorothrin?

Momfluorothrin is a new pyrethroid insecticide that kills insects and spiders on contact. It may be used indoors and outdoors at residential locations. It rapidly immobilizes most pests after treatment, which may reduce the distance the target pest travels after treatment. This may allow easier disposal of dead insects and spiders.

Health Considerations

Can Approved Uses of Momfluorothrin Affect Human Health?

Products containing momfluorothrin are unlikely to affect your health when used according to label directions.

Potential exposure to momfluorothrin may occur when handling and applying end-use products containing momfluorothrin. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient momfluorothrin was of high acute toxicity by the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of low acute toxicity dermally and through inhalation exposure. Momfluorothrin was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction.

There are three manufacturing concentrates (Sumifreeze Manufacturing Use Product, MGK 2987 and MGK 2983) containing momfluorothrin. Sumifreeze Manufacturing Use Product was of low acute toxicity via the oral and dermal route of exposure, but was slightly toxic via the inhalation route. It was non-irritating to the skin, but mildly irritating to the eyes, and did not cause an allergic skin reaction. Based on these findings, the signal word and hazard statements "CAUTION – POISON" and "EYE IRRITANT" are required on the product label.

MGK 2987 was of moderate acute toxicity via the oral route of exposure, was slightly toxic via the inhalation route, and was of low toxicity via the dermal route. It was mildly irritating to the skin and eyes, but did not cause an allergic skin reaction. Based on these findings the signal word and hazard statements "WARNING – POISON" and "EYE AND SKIN IRRITANT" are required on the product label.

MGK 2983 was of moderate acute toxicity via the oral route of exposure, but was of low acute toxicity via the dermal and inhalation routes. It was non-irritating to the skin and eyes, but produced an allergic skin reaction. Consequently, the signal word and hazard statements "WARNING – POISON" and "POTENTIAL SKIN SENSITIZER" are required on the product label.

There are four end-use products (Momfluorothrin Flying and Crawling Insect Killer Spray, MGK 29831, MGK 29871, MGK 29872) containing momfluorothrin.

Momfluorothrin Flying and Crawling Insect Killer Spray was of low acute toxicity via the oral and dermal routes of exposure, and was of slight toxicity via the inhalation route. Consequently the signal word and hazard statement "CAUTION – POISON" are required on the label. It was minimally irritating to the skin, not irritating to the eyes and did not cause an allergic skin reaction.

MGK 29831 was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and eyes and produced an allergic skin reaction. Consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the product label.

MGK 29871 was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was not irritating to the skin and eyes and did not cause an allergic skin reaction.

MGK 29872 was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and eyes and did not cause an allergic skin reaction.

Health effects in animals given repeated doses of momfluorothrin primarily involved effects on the liver and nervous system. There was no indication that momfluorothrin caused damage to the immune system. Momfluorothrin did not cause birth defects in animals and there were no effects on the ability to reproduce. There was no evidence to suggest that momfluorothrin damaged genetic material. Momfluorothrin did, however, cause liver tumours in rats following prolonged dosing.

When momfluorothrin was given to pregnant or nursing animals, decreased body and spleen weights were observed in the juvenile animal at doses that were not toxic to the mother, suggesting that the young may be more sensitive to momfluorothrin than the adult animal.

The risk assessment protects against the effects of momfluorothrin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential exposure is not of concern provided that directions specified on the label are observed.

Residential exposure to adults applying momfluorothrin and contacting treated surfaces is not expected to result in unacceptable risk when momfluorothrin is used according to label directions. Exposure to youth (11 < 16 years) and children (1 < 2 years) contacting treated surfaces is not of concern when momfluorothrin is used according to label directions.

Occupational Risks From Handling Momfluorothrin

The momfluorothrin products are domestic class end-use products so exposure to occupational users is not of concern.

Environmental Considerations

What Happens When Momfluorothrin is Introduced Into the Environment?

Momfluorothrin will not persist in soil and water. As the environmental exposure to momfluorothrin will be very limited if used according to the proposed label, the risk to organisms in the environment is negligible.

Products containing momfluorothrin are proposed to be used as a crack and crevice or spot treatment (only) indoors and outdoors to control flying and crawling insects. Insects are controlled by direct contact with the insecticide when it is sprayed from an aerosol can. These products may be used to control insects outside at residential locations. The contents of insect nests are not to be treated with these products. Low environmental exposure from momfluorothrin is expected from these uses as a household aerosol spray because only small, limited areas are being treated where insect pests are visible. If momfluorothrin enters the environment, it will break down quickly in soil and water by microorganisms. Breakdown of momfluorothrin in water in the presence of light will be limited. Momfluorothrin binds strongly to soil and is unlikely to bioaccumulate in fish.

Momfluorothrin is practically non-toxic to terrestrial organisms that were studied, but is highly toxic to honeybees when they are directly contacted with the insecticide spray. This chemical is also very highly toxic to aquatic organisms, such as fish and aquatic invertebrates. Considering that momfluorothrin is proposed as a household aerosol spray, the potential for exposure of non-target terrestrial and aquatic organisms in the environment is expected to be very limited. Therefore, risk to non-target organisms is also expected to be minimal.

Value Considerations

What Is the Value of Momfluorothrin Flying and Crawling Insect Killer Spray?

Momfluorothrin Flying and Crawling Insect Killer Spray kills ants, cockroaches, several fly species, several stinging insect species and spiders found indoors and outdoors at residential locations.

Momfluorothrin Flying and Crawling Insect Killer Spray is a ready-to-use spray that combines momfluorothrin with another pyrethroid, d-phenothrin. The combination of these two active ingredients demonstrated improved efficacy against insects and spiders compared to either active ingredient alone.

What Is the Value of MGK 29831?

MGK 29831 kills several fly and moth species found indoors and outdoors at residential locations.

MGK 29831 is a ready-to-use spray that combines momfluorothrin with a synergist, piperonyl butoxide. The addition of piperonyl butoxide increased the efficacy of momfluorothrin against house flies compared to momfluorothrin alone.

What Is the Value of MGK 29871 and MGK 29872?

MGK 29871 and MGK 29872 kill several stinging insect species found indoors and outdoors at residential locations.

MGK 29871 and MGK 29872 are ready-to-use sprays that combine momfluorothrin with another pyrethroid, d-phenothrin. The combination of these two active ingredients demonstrated improved efficacy against insect pests compared to either active ingredient alone.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Momfluorothrin Flying and Crawling Insect Killer Spray, MGK 29831, MGK 29871 and MGK 29872 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To avoid direct contact with momfluorothrin on the skin, by inhalation, or through incidental-oral ingestion, follow the label directions.

Environment

Hazard label statements are required to inform users that these products are toxic to aquatic organisms and bees.

Label statements also limit the outdoor use of momfluorothrin-containing products to crack and crevice or spot treatments, and indicate no direct application to water is allowed.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-21, *Momfluorothrin*) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this Registration Decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada website (Request a Reconsideration of Decision), or contact the PMRA Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

Comments
PMRA received comments regarding errors in the repeat dose metabolism and pharmacokinetics study and the rat bone marrow micronucleus assay, Table 3: Toxicity Profile of Technical Momfluorothrin, Appendix I of the PRD2014-21.

Response
PMRA revisited the data and agreed to make the following amendments to the table entry for the repeat-dose toxicokinetics study and for the rat bone marrow micronucleus assay:

Study Type/Animal/PMRA #	Study Results
Metabolism and pharmacokinetics (repeat administration) Wistar rat PMRA #2299081	Excretion in urine and feces was not altered by repeated administration. Excretion was rapid, and by the third dose radioactivity was excreted in urine and feces at an almost constant rate (approximately 38% and 51% respectively). Residual radioactivity in the carcass was less than 0.1% at the end of the study. Tissue concentrations remained relatively constant at 6 hrs following dosing at 10, 16, or 21 doses. Concentration in plasma was no longer detectable at 168 hrs after the last dose. Accumulation of radioactivity to tissues was considered low. Distribution of radioactivity and the composition of metabolites in tissues showed almost the same pattern during repeated administration.

Study Type/Animal/PMRA #	Study Results
Rat bone marrow micronucleus assay (gavage) Sprague Dawley rats PMRA #2299085	Negative In males, death (1/5 animals), tremors and soft stools were noted at 600 mg/kg bw in the range-finding study. Although death was not observed at 600 mg/kg bw in the definitive study, tremors were observed at ≥ 300 mg/kg bw, and soft stools were observed at ≥ 150 mg/kg bw. In females, death (1/5 animals) and tremors were noted at 200 mg/kg bw in the range-finding study. In the definitive study, deaths (2/20 animals) and tremors were noted at 200 mg/kg bw.